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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/831,180 | 08/03/2001 | Chiaki Senoo | 50026/027001 | 1189 |
| 21559 | 7590 | 10/04/2005 | EXAMINER | |
| CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110 | | | SWOPE, SHERIDAN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1656 | |
| DATE MAILED: 10/04/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/831,180 | Applicant(s) SENOO ET AL. | |
| | Examiner Sheridan L. Swope | Art Unit 1656 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

20

DETAILED ACTION

Claims 1-15 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-4, drawn to a protease polypeptide.

Group II, Claims 5-8 and 15, drawn to a polynucleotide, vector, host cell and method of making the encoded protease polypeptide.

Group III, Claim 9, drawn to a method for identifying a substrate of a protease polypeptide.

Group IV, Claim 10, drawn to a substrate of a protease polypeptide.

Group V, Claim 11, drawn to a method for identifying a modulator of a protease polypeptide.

Group VI, Claim 12, drawn to an inhibitor of a protease polypeptide.

Group VII, Claim 13, drawn to an antibody to a protease polypeptide.

Group VIII, Claim 14, drawn to a method for detecting a protease polypeptide.

For each of Inventions I-VIII above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Inventions I-VIII and one of Inventions (A)-(E).

(A.) SEQ ID NO: 2

(B.) SEQ ID NO: 4

(C.) SEQ ID NO: 6

(D.) SEQ ID NO: 8

(E.) SEQ ID NO: 10

The inventions listed as Groups I-VIII (A)-(E) do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The technical feature linking Groups I-VIII (A)-(E) appears to be that they all relate to protease polypeptides. However, protease polypeptides were well known in the art. Moreover, Sigma, Inc 1997 teach a partial peptide of a protease polypeptide, which anticipates Claim 3. Therefore Groups I-VIII (A)-(E) share no special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Furthermore, the products of Groups I, II, IV, VI, and VII (A)-(E) do not share a special common structural and functional feature while, the methods of Groups III, V, and VIII (A)-(E) do not use the same reagents or produce the same results. In addition, the methods of Groups III, V, and VIII (A)-(E) do not comprise all of the methods for making or using the products of Groups I, II, IV, VI, and VII (A)-(E). Accordingly, Groups I-VIII (A)-(E) are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Searching more than one of Groups I-VIII (A)-(E) would represent a burden on the Office for the following reasons. Because the products of Groups III, V, and VIII (A)-(E) do not share a special structural and functional feature, a search for any one said product would not encompass a search for any other said products. Thus, a search for more than one of the products of Groups III, V, and VIII (A)-(E) would be a burden on the Office. In addition, the search of Group II would not encompass a search for Group I, which would include searching the prior art

Art Unit: 1656

for teachings of the purified protein, while, a search for Group I, class 435, subclass 226, would not encompass a search for Group II, class 536, subclass 23.2. Thus, a search of either Group I or II would not encompass a search for the other invention and searching both inventions would be a burden on the Office. A search for any one of the methods of Groups III, V, and VIII (A)-(E) would not encompass a search for any other said methods because the methods do not share a special technical feature of steps and products used, or results produced. Thus, the search for more than one of Groups III, V, and VIII (A)-(E) would be a burden on the Office. A search of any one of the products of Groups III, V, and VIII (A)-(E) would not encompass a search of any of the methods of Groups III, V, and VIII (A)-(E), or vice versa, because said methods are not the only methods of making or using said products. Thus, a search of any one of the products of Groups III, V, and VIII (A)-(E) with any of the methods of Groups III, V, and VIII (A)-(E) would be a burden on the Office.

These inventions lack Unity of Invention for the reasons given above. Furthermore, each invention has acquired a separate status in the art due to their recognized divergent subject matter and, thus, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. 821.04, *In re Ochiai*, and *In re Brouwer*). Process claims that depend from or otherwise include all the limitations of the patentable product

Art Unit: 1656

will be entered as a matter of right, if the amendment is presented prior to final rejection or allowance, whichever is earlier. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. To be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan L. Swope, Ph.D.
Art Unit 1656


SHERIDAN SWOPE, Ph.D.
PATENT EXAMINER